

PCT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION

(PCT Rule 66)

To: K. DAVID CROCKETT
CROCKETT & FISH
4093 TROPICO WAY
LOS ANGELES, CALIFORNIA 90065

Date of Mailing
(day/month/year) **22 FEB 1999**

Applicant's or agent's file reference
212/113 PCT

REPLY DUE within **TWO** months
from the above date of mailing

International application No.
PCT/US98/08111

International filing date (day/month/year)
20 APRIL 1998

Priority date (day/month/year)
05 JUNE 1997

International Patent Classification (IPC) or both national classification and IPC
IPC(6): A61F 2/00; and US Cl.: 607/101

Applicant
ADIANA, INC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **05 OCTOBER 1999**

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

ROSALIND KEARNEY

Telephone No. (703) 308-2711

I. Basis of the opinion

1. This opinion has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

☒ the international application as originally filed.

☒ the description, pages 1-23, as originally filed.

pages NONE, filed with the demand.

pages NONE, filed with the letter of _____

☒ the claims, Nos. 1-12, as originally filed.

Nos. NONE, as amended under Article 19.

Nos. NONE, filed with the demand.

Nos. NONE, filed with the letter of _____

☒ the drawings, sheets/fig 1-9, as originally filed.

sheets/fig NONE, filed with the demand.

sheets/fig NONE, filed with the letter of _____

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig NONE

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1, 2, 5, 9-12</u>	YES
	Claims <u>3, 4, 6-8</u>	NO
Inventive Step (IS)	Claims <u>1, 2, 9, 10, 12</u>	YES
	Claims <u>3-8, 11</u>	NO
Industrial Applicability (IA)	Claims <u>1-12</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 3-4 and 6-8 lack novelty under PCT Article 33(2) as being anticipated by Zipes et al. Zipes et al. disclose a device for application of RF energy to the pathway within the body comprising a catheter, an electrode assembly (20) releasably attached to the distal end of the catheter, and a release mechanism as described in column 4 line 16. Fig. 4 illustrates the particular details of the electrode assembly.

Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over Zipes et al. Zipes et al. explicitly teach all of the limitations of the claims except a coating of ingrowth compound on the plug. It is an old, and well-known practice in the art to coat medical devices used internally. Many coatings include bio-compatible materials which promote the bodies acceptance of the foreign device. Since the main function of the Zipes et al. apparatus is to attach an electrode to internal tissue it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the device with an ingrowth promoting compound to assist the body in accepting, and maintaining the device.

Claims 11 lacks an inventive step under PCT Article 33(3) as being obvious over Wilk et al. Wilk et al. teach all of the limitations of the claim except a locking mechanism releasably securing the catheter to a speculum. The use of vaginal speculums for the purpose of examination, and surgical procedures is a widely accepted medical practice. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a speculum for use with the Wilk et al. apparatus to provide a means for maintaining the vagina in an open position. It would have been furthermore obvious to provide some type of locking assembly on the device to use in conjunction with the speculum to insure that the speculum remains in place while the surgery is being performed.

Claims 1, 2, 9, 10 and 12 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or
(Continued on Supplemental Sheet.)

WRITTEN OPINION

International application No.

PCT/US98/08111

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

TIME LIMIT:

THE TIME LIMIT SET FOR RESPONSE TO A WRITTEN OPINION MAY NOT BE EXTENDED. 37 CFR 1.484(D). ANY RESPONSE RECEIVED AFTER THE EXPIRATION OF THE TIME LIMIT SET IN THE WRITTEN OPINION WILL NOT BE CONSIDERED IN PREPARING THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (CONTINUED):

FAIRLY SUGGEST DELIVERING RADIO FREQUENCY ENERGY CAUSING THE TISSUE TO COLLAPSE, AND A RELEASE MECHANISM AS CLAIMED OR ADVANCING A CATHETER HAVING A DETACHABLE ELECTRODE THROUGH THE VAGINA.

NEW CITATIONS

NONE